

REMARKS

To expedite prosecution, claims 1-5, 7, 15-16, 18-20, 24-31, 36-46 have been cancelled. Applicants reserve the right to resubmit these claims in future continuing applications or by entering the U.S. national stage with the PCT application based upon the present application. Claims 5 and 35 have also been amended to expedite prosecution of more urgent material, and Applicants reserve the right to resubmit any surrendered subject matter in future continuing applications or by entering the national stage with the PCT application based upon the present application. The remaining amendments were made to correct dependency upon cancelled claims.

Claim Objections

The objection to claim 24 is no longer relevant because the claim has been cancelled.

The objections to claims 3, 4, 37, 38 and 42 and 43 are also no longer relevant because the claims have been cancelled. However, Applicants point out for future prosecution that the observation that “[t]hese compounds have the same chemical structure and only differ in their synthesis where one is synthetic and the other is naturally occurring” is erroneous. Rather, bimatoprost is only one species of the substantially larger prostamide genus.

The objections to claim 25 and 20 are also no longer relevant because the claims have been cancelled.

Claim Rejections – 35 USC § 112

Claim 1 was rejected under 35 U.S.C. 122, second paragraph. Since this claim has been cancelled, this rejection is no longer relevant.

Claim Rejections -35 USC § 103

While Applicants do not concede that a prima facie case of obviousness has been made against the claims as they stood before amendment, this will not be dealt with for the cancelled claims. The prima facie case of obviousness of the claims as they stand rests upon Ikari (US 6,232,343), Singh (US 2003/0232089), and Hellberg (US 6,646,001). According to the Office Action, Ikari teaches "a method of adding cyclodextrin to prostaglandin drug formulations to reduce irritating side effects such as hyperemia." The Office Action further asserts that Singh provides the addition of the viscosity increasing agent. Finally, the use of bimatoprost in that formulation is provided by Hellberg.

The prima facie case of obviousness of the Office Action fails for the claims as they now stand because it does not provide a motivation to combine the teachings of Singh with those of Hellberg and Ikari. Bimatoprost is highly effective at reducing intraocular pressure as marketed, and bioavailability is not a problem with the drug. Singh teaches that the viscosity enhancing agent is useful in reducing precorneal drug loss to improve bioavailability of the drug. However, since bioavailability of bimatoprost is not a problem, there is no apparent need to include a viscosity enhancing agent. Thus, there is no suggestion or motivation to combine Singh with the other references, and a prima facie case of obviousness has not been made for the claimed combination.

In light of the points made above and the amendments made to the claims, the Applicants assert that all of the claims are patentable as they stand, and therefore respectfully request that the Examiner remove the rejections and pass the application to issue.

Respectfully submitted,

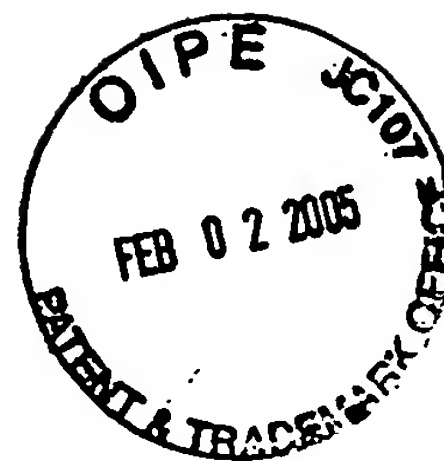


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CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. §1.10

I hereby certify that this Transmittal Letter and Reply Under 37 CFR § 1.111 and the documents referred to as enclosed herein are being deposited with the United States Postal Service on **February 2, 2005** in an envelope as "Express Mail Post Office To Addressee" mailing label number EV295681845US with sufficient postage for Express Mail addressed to Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: February 2, 2005

Susan Bartholomew

Name of person mailing paper

A handwritten signature in cursive script, appearing to read "Susan Bartholomew", written over a horizontal line.

Signature of person mailing paper